DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 9, 2015

Zibo Ling Yun Medical Products Co., Ltd.
C/O Mr. Ray Zhou
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Ave
Chino, CA 91710

Re: K143340
Trade/Device Name: Powder-free Vinyl Patient Examination Gloves, Yellow Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: June 2, 2015
Received: June 5, 2015

Dear Mr. Zhou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143340

Device Name
Powder-free Vinyl Patient Examination Gloves, Yellow Color

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary
Attachment

510 (K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

   Zibo Ling Yun Medical Products Co, Ltd
   NO.318 Yuming Road Zibo Industrial Park
   Zibo City, Shandong China

Date summary prepared: July 8, 2015

2. **Name of the Device:**

   Zibo Ling Yun Medical Products Co, Ltd
   Powder-free Vinyl Patient Examination Gloves, Yellow Color

3. **Common name/classification name of the Device:**

   Powder-free Vinyl Patient Examination Gloves, Yellow Color

4. **Contact Person:**

   Ray Zhou, Tel: 909-548-4828
   Email:rayzhou@basicmedical.com

5. **Predicate Device Information:**

   Shijiazhuang Hongxiang Plastic Products Ltd.
   Synthetic Powder-Free Vinyl Patient Examination Gloves (K992821)

6. **Device Description:**

   Subject device: Powder-free Vinyl Patient Examination Gloves, Yellow Color

   i. Principal operation of the glove
   A disposable device intended for medical purposes that is worn upon the examiner's hands or finger

   ii. Mechanism of action for achieving the intended effect
   Prevent contamination between patient and examiner

iii. Reference to the standards
Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5, meet ASTM-D-5250-06. The residual powder testing conforms with standards of ASTM D-6124-06.

iv. Biocompatibility results
Not an irritant; Not a sensitizer

v. Bench testing
N/A

7. **Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

8. **Comparison to Predicate Devices:**

Zibo Ling Yun Medical Products Co, Ltd Powder-free Vinyl Patient Examination Gloves, Yellow Color are similar to the Shijiazhuang Hongxiang Plastic Products Ltd. Synthetic Powder-Free Vinyl Patient Examination Gloves (K992821)

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device (K143340)	Predicate Device (K992821)
Device Description	Zibo Ling Yun Medical Products Co, Ltd Powder-free Vinyl Patient Examination Gloves, Yellow Color	Shijiazhuang Hongxiang Plastic Products Ltd. Synthetic Powder-Free Vinyl Patient Examination Gloves
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner
Basic Design	Cover the hand and wrist area. Covers have separate sheaths or openings for each finger and the thumb.	Cover the hand and wrist area. Covers have separate sheaths or openings for each finger and the thumb.
Regulation #	21 CFR 880.6250	21 CFR 880.6250
Device Class	Class I	Class I

Product Code:	LYZ	LYZ
Labeling	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
Physical Properties: Length on Large Size	Confirmed with ASTM D5250-06	Confirmed with ASTM D5250-06
Physical Properties: Width of Palm on Large Size	Confirmed with ASTM D5250-06	Confirmed with ASTM D5250-06
Physical Properties: Palm Thickness	Confirmed with ASTM D5250-06	Confirmed with ASTM D5250-06
Physical Properties: Fingertip Thickness	Confirmed with ASTM D5250-06	Confirmed with ASTM D5250-06
Non-Clinical results: Residual Powder	<2 mg per glove and meet the requirement of ASTM D6124-06.	Meet ASTM D6124-06
Non-Clinical results: Pinhole Results	Meet ASTM-D-5250-06	Meet ASTM-D-5250-06
Non-Clinical results: Dermal Sensitization	Not a sensitizer	Not a sensitizer
Non-Clinical results: Primary Skin Irritation	Not an irritant	Not an irritant
Dimensions with Tolerances: Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Meet ASTM D5250-06	Substantially equivalent
Dimensions with Tolerances: After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Meet ASTM D5250-06	Substantially equivalent
Summary of comparison	Zibo Ling Yun Medical Products Co, Ltd Powder-free Vinyl Patient Examination Gloves, Yellow Color (subject device) and Shijiazhuang Hongxiang Plastic Products Ltd. Synthetic Powder-Free Vinyl Patient Examination Gloves (predicate device) are substantially equivalent in all technological characteristics, has similar intended uses and technological characteristics and performed similar to the predicate	

9. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Zibo Ling Yun Medical Products Co, Ltd glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization testing was conducted with results showing no primary skin irritant or sensitization reactions.

No special labeling claims. Our gloves are "powder-free." They contain no more than 2 mg powder per glove.

10. **Sterilization**

Not sterilized

11. **Patient Contact**

Patient contact is limited for surface-contacting and has less than 24 hour duration.

12. **Discussion of Clinical Tests Performed:**

Not Applicable

13. **Conclusions:**

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe and as effective, and performs as well as the legally marketed device.